DEPARTMENT OF HEALTH AND HUMAN SERVICES

939084

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

March 14, 2003

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 03-15

Avelino A. Vieira, Owner
Alvieira Dairy
P.O. Box 380
Wendell, Idaho 83355

WARNING LETTER

Dear Mr. Vieira:

An inspection at your dairy located at 1856 East 3400 South, Wendell, Idaho, by our investigator on February 3 and 6, 2003, confirmed that you offered an animal for sale for slaughter as food in violation of Section 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

On or about March 19, 2002, you sold a downer cow with back tag #82 VL 7406 identified on USDA Case #02-1379-ID, Form #433475, for slaughter as human food to [redacted] USDA analysis of tissue samples collected from that animal identified the presence of tilmicosin in the liver at 1.93 parts per million (ppm), in the muscle at 2.11 ppm, and in the kidney at 15.92 ppm. A tolerance of 1.2 ppm has been established for residues of tilmicosin in liver tissues of cattle, Title 21 Code of Federal Regulations, Part 556.735. There is no tolerance established for residues in the muscle or kidney tissues. The excess residue of this drug in edible tissue from these animals causes the food to be adulterated within the meaning of Section 402(a)(2)(C)(ii) of the Act.

Our inspection also found that you hold animals under conditions that could allow medicated animals, bearing potentially harmful drug residues, to enter the food supply. For example, you lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete potentially hazardous residues of drugs from edible tissues. Additionally, you have no animal medication records that would identify which animals have been medicated, what date the treatment was

administered, what type and dosage of medication had been used, and the required withdrawal periods for the medication used. You also do not have an adequate system for assuring that drugs are used in a manner not contrary to the directions contained in their labeling. Food from animals held under such conditions is adulterated within the meaning of Section 402(a)(4) of the Act.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for assuring that your overall operations and the foods you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Federal Food, Drug, and Cosmetic Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing, within fifteen (15) working days of the receipt of this letter, of the specific steps you have taken to bring your firm into compliance with the law. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have questions regarding any issue in this letter, please contact Lisa M. Elrand, Compliance Officer at (425) 483-4913.

Sincerely,

Charles M. Breen
District Director

Enclosure:
Form FDA 483